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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,663	06/27/2001	Todd A. Hall	7883.0005-04	5780
22852	7590	12/11/2003	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			DAVIS, DANIEL J	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/891,663

Applicant(s)

HALL ET AL.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69-79 and 81-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-79 and 81-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69-74, 76-79, 81-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Maki et al. (US 6,261,260). Maki discloses a delivery catheter (Fig. 11) comprising an elongate tubular body 3, a proximal anchoring member 2, and a distal steering member 2. Maki discloses the use of one balloon that is used to steer the catheter tip. The Maki device is a balloon with areas of greater and lesser inflatability, which steer the catheter. The inflatable balloon may be divided into two equal parts each having an area of greater inflatability. The result is a proximal anchoring member and a distal steering member. The two members push against opposite sides of the vessel wall to steer the catheter tip. (Further explanation is added in the Response to Arguments.) Although the balloon is cylindrical, the anchoring member and the steering member are mounted on opposite sides of the tubular body. The tubular body is formed of a flexible polymer (Col. 9, lines 21-27).

Claims 69-78 and 81-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Grinfeld et al. (US 5,312,344). Grinfeld discloses a deliver catheter (Fig. 2) comprising a tubular body 6, an anchoring member 10, and a steering member 9. As illustrated, the steering member 9 acts to change the direction of the distal tip. The role as steering member is accentuated considering that as the catheter is pushed distally while the balloons are in the inflated state, the steering member acts to redirect and steer the catheter as it moves through the ascending aorta. Since the steering member and the anchoring member both contact the vessel wall throughout an entire radial 360 degrees, the two members do engage oppositely located vessel wall portions. Likewise, the members are mounted on opposite sides of the tubular member, even though they also have some sides in common.

Furthermore, when placed into the vessel prior to balloon inflation, the distal end of Grinfeld's catheter "a" would inherently not be located directly in the center of the vessel. Hence, as the balloons inflate, the portion of the balloons nearest the vessel wall will push against the wall and turn the distal end of the catheter in the proper direction.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(c) which forms the basis for all obviousness rejections set forth in this Office action:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 94-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maki in view of Wilk (US 5,429,144). Maki disclose a steerable balloon catheter tube but fail to disclose a method of advancing a medical device/stent through the lumen of the deliver catheter and out the distal end. Nevertheless, Wilk discloses a method of advancing a stent through a steerable catheter at an angle with the coronary vessel wall and implanting it in a myocardial wall as a means for deploying a stent (Col. 9, lines 1-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Makis' steerable balloon catheter as taught by Wilk to implant a stent in the myocardial wall between the coronary vessel and a chamber of the heart.

***Response to Arguments***

Applicants' arguments filed September 17, 2003 have been fully considered, but are not persuasive. The Maki device is used to direct a catheter when guided through the branching of the vascular system. The curved balloon section directs the head of the catheter. The balloon portion is not capable of re-directing the entire catheter. The

head is oriented to enter a new branch vessel. However, the proximal end of the catheter continues to force the catheter head along the original path. As a result, the catheter head engages the vessel wall within the new branch. Further advancement of the catheter forces the balloon portion against the vessel wall. The vessel wall in turn pushes back on the catheter and steers it down the path of the new branch vessel. Hence, Maki's catheter does use the vessel walls for turning the catheter.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

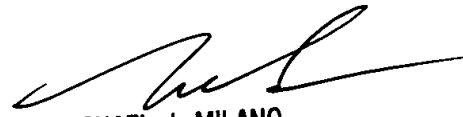
Art Unit: 3731

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
DJD  
December 4, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700